Remarks to the Michigan House of Representatives February 14, 2004
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Mr. Chairman, members of the committee, my name is Doug O'Brien and I am the regional director of the U.S. Department of Health and Human Services for region five, serving the states of Ohio, Indiana, Illinois, Wisconsin, Minnesota and Michigan. I greatly appreciate the opportunity to be here today on behalf of HHS Secretary Mike Leavitt, to give an overview of some of the federal efforts to prepare for a potential pandemic outbreak in the United States.

The secretary views this as one of the top priorities of the department and is in the process of traveling to all 50 states to participate in planning summits with state leaders in government, health care and the private sector. Governor Granholm has extended an invitation to the secretary to Michigan's summit on the 15th of March in the Detroit area.

And while considerable attention has been paid to the state public health and emergency management agencies with operational responsibility for this issue, we understand that the legislature plays a crucial role in the authorization and appropriations for this undertaking.

Last fall the US Department of Health and Human Services released its National Pandemic Influenza Plan. This document was not thrown together overnight, but represents several years of intense work by some of the leading experts in a wide range of public health specialties. The administration has worked behind the scenes to ramp up our nation's

preparedness to deal with any major public health emergency. This is the result of both the various public health components of the post 9-11 environment with issues such as anthrax exposure; as well as experiences with illnesses such as SARS and the West Nile Virus.

And **now** the international attention on Avian Influenza has focused the spotlight on our pandemic preparations at all levels of American government. It is critical to remember, that throughout our history, public health has been and must fundamentally remain, a local function. State and local officials, like yourselves, in partnership with the professionals you employ, are uniquely qualified to prepare and implement the best plans--to address the unique needs of your population.

Of course the federal government has a huge role to play in preparedness as well. International efforts, research, policy development and planning, communications, and logistics are just the major components of the national government's role. And I want to briefly outline some of the highlights of the federal roles and hopefully answer any questions you may have.

Nearly two years ago, the Centers for Disease Control and Prevention began working directly with states to help them develop preparedness plans of their own. It has been the goal of the administration to provide strong leadership in the development of best practices and interoperable planning that recognizes the need for close cooperation. And our HHS plan has done that. Many states are currently analyzing their plans and performing gap analyses to find ways they can work with CDC and the Department of Health and Human Services to integrate their preparations.

As part of the federal effort to help state and local governments improve their preparations and integrate their efforts with the federal plan, the administration's pandemic preparedness plan includes an initial $100 million in direct funding for planning assistance to state and local governments in fiscal year 2006, including nearly $3 million for the state of Michigan. In addition, another $250 million has been appropriated to be distributed to the states contingent on the progress of ongoing planning efforts.

But the extent of federal assistance to local public health systems doesn't end there by any means.

The plan allocates $212 million to expand our Strategic National Stockpile at the CDC. This program provides for equipment such as ventilators and other key items that can be moved rapidly to any part of the country to help deal with a public health emergency. This material can be plugged into local public health systems in a matter of hours.

Moving forward, the administration also provides new funding for CDC surveillance efforts to be conducted in close cooperation with state and locals health agencies. CDC is also funding a staff position with the state to coordinate surveillance efforts and has put in place 35 quarantine centers at major points of entry to the US, including a center at the Detroit airport that opened in December.

And in one of our most significant commitments to the states, the federal plan provides over 1.4 billion dollars of spending on antiviral medicines that will directly benefit state and local public health systems and make available

to public health agencies throughout Michigan, medications that can help save thousands of lives in the event of a pandemic outbreak.

In addition to those proposals that directly provide added resources in money and materiel to state and local governments, the federal pandemic plan undertakes an unprecedented effort to change the very nature of the science of vaccinations. This multi-billion dollar effort, which only the federal government has the resources and infrastructure to take on, has the potential to impact every single man, woman and child on the planet.

Experts around the globe are engaged in discussion, debate and research on how to best provide vaccine protection against any potential pandemic influenza. There are many ideas and numerous obstacles. There are two huge obstacles in particular that stand in the way of being able to produce and stockpile enough vaccines to protect people from dangerous flu strains.

The first is that the most effective flu vaccines are created directly from the specific strain of influenza from which you need protection. As a result, the **best** vaccine cannot be created until the specific flu manifests itself in the human population. This means, with current technology, it can take many months before a vaccine can be developed and mass produced.

The second major obstacle is the current way we manufacture vaccines. In what is called "egg based" production, vaccine doses are actually grown in fertilized chicken eggs. This process takes more time and requires, obviously, a significant supply of eggs. And it stands to reason that in an avian influenza pandemic, eggs might not be readily available in the millions.

To address these problems, the federal government, in its pandemic readiness plan, seeks to develop the technology to produce vaccines on a cellular basis that will allow for the production of hundreds of millions of vaccine doses in the span of a few months.

As this new technology is being perfected, HHS will concurrently stockpile currently available flu vaccines, purchase excess capacity from manufacturers, invest in retrofitting of production facilities for emergency vaccine production and enhance the availability of antigens that improve the effectiveness of vaccines.

Additionally, HHS, through CDC and the National Institutes of Health are working on research to create universal flu vaccines that possess proven efficacy against all type A strain viruses.

In all, over 4 and a half **billion** dollars will be invested in production, stockpiling, research and enhancement of influenza vaccines.

Another issue that is widely discussed in relation to influenza is the availability of antiviral treatments. And the administration is making great progress on this front as well. But it is important to make a few distinctions first. Antivirals can be an important part of any pandemic preparation plan. But antivirals are not a panacea. Simply having an antiviral dose for every person will not protect us from a pandemic. In fact, relying on antivirals can lead to other problems--such as the emergence of influenza with a natural resistance to antivirals such as Relenza or Tamiflu. So while the administration is committed to building stockpiles of antivirals and making them available as ***one of many tools*** to combat pandemic, to measure

readiness by number of antiviral doses is a simplistic and misleading approach.

As its immediate goal, the administration is seeking to have available, antiviral doses for 25% of the American population. These doses will be divided into three major categories:

First, over 40 million doses will be available for state and local public health systems to treat individuals according to the prioritization plan ***they*** develop. HHS has provided significant guidance for governments to develop these prioritization plans. They may include those with the greatest medical susceptibility to influenza, such as those with respiratory illnesses or autoimmune deficiencies; those most susceptible to exposure, such as health care workers and first responders; and those with infrastructure-critical jobs, such as utility and transportation workers and of course, those who are producing antivirals and vaccines. But it is important to note that these plans are local in design and implementation and there is not a cookie-cutter federal directive that takes the place of local planning.

These antivirals on hand, ***and*** those being acquired by the federal government for the Strategic National Stockpile at a cost of nearly $800 million, will be ***given*** to state and local public health systems for them to distribute in accordance with these plans.

A second stock of antivirals, approximately 6 million doses, will be held for prophylaxis or containment use. This is known as a "quenching" effort where, for example, were an outbreak to occur in one or two cities, significant numbers of doses could be moved to those location rapidly to

undertake a major containment effort to minimize the chance of widespread expansion of the disease.

And third, the federal government will stockpile additional doses, approximately 31 million, that can be obtained by state health systems on a cost sharing basis with the federal government.

Of course, ***before*** any illness that threatens humans can develop or spread to our shores, the federal government is working diligently and investing significantly in efforts to curtail avian flu outbreaks, particularly in Southeast Asia. Over $30 million dollars are to be spent on clinical trials and studies of new vaccines and vaccine manufacturing in countries like Vietnam and Thailand. These efforts build on those undertaken over the past year to improve situational awareness around the world and intergovernmental cooperation on influenza surveillance. HHS Secretary Mike Leavitt and his colleagues from the G8 nations are working closely with the governments of Asia on enhancing surveillance, vaccination and treatment programs that seek to minimize the spread of avian flu and reduce the chance of an outbreak among humans.

In recent months we have seen new cases of H5N1 influenza confirmed in new areas such as Eastern Europe, Turkey and Iraq. The WHO and CDC are very involved in examining these cases and determining origins and implications of these cases. It is important to note that there are still no cases of human to human transmission of the illness and that bird migration patterns are likely responsible for these new cases.

But while we must remain vigilant in working internationally to prevent a pandemic outbreak, we must continue our domestic preparations so that when the next pandemic illness does arise, whether in a few years or a few decades, we have the knowledge, the technology, the infrastructure and the public awareness that enables us as a nation to fight it most effectively.

It is important to remember that pandemic preparedness ranges from the biggest picture issues down to our personal responsibilities as Americans. At every level lie certain responsibilities. And the most important of those responsibilities are planning, preparation and transparency. ***Now***, while there is ***not*** an imminent threat to our population, is the time to plan for unprecedented surge capacities--to determine what sources of supplies exist--to plan for the best ways to contain or minimize the spread of disease--and to do so at the ***local*** level. If there is a pandemic event, it should be ***local*** officials who decide whether or not schools should remain open. Local officials are best able to determine where to treat the sick and where, and to whom antivirals and vaccines will be administered. Local officials know what their capacities are, what unique local conditions exist and how to best involve the people in the planning process.

Some of these decisions will be hard. How DO we deal with surge capacity issues? How DO we prioritize the distribution of vaccines and other treatments? Should the federal government make these decisions for everyone in Michigan?

HHS has provided guidance on how to structure state and local plans and what issues need to be addressed by governments, providers and the private sector. But it won't dictate where Ingham Medical Center should deploy its

staff. It won't determine what building the Kent County Health Department should use to distribute vaccines. And it won't decide how the Detroit Police Department will respond if 30% of its officers are sick with the flu. And I don't think anyone wants Washington to make those decisions. Working together, we can achieve coordination that will make plans at the federal, state, local and individual level more effective, and we can try to anticipate unforeseen problems now, when we can work to prepare for them.

The state of Michigan and the Department of Community Health have developed a pandemic plan as a annex to the state's All Hazards Response Plan. It provides valuable guidance to local health departments and outlines state priorities in many preparation and response categories. Of course, the success of such a plan partly relies on the cooperation of all levels of government. HHS and CDC stand ready to work with states to evaluate and enhance interoperability of the Michigan and federal plans, and we encourage the state to undertake the same outreach to county and municipal agencies, as well as provider and private business associations. For states, local governments, private businesses, healthcare providers, schools, families and community organizations, HHS and CDC have developed checklists that are an excellent way to evaluate existing plans and to develop new plans. These checklists can be found at www.pandemicflu.gov.

In conclusion, the Department of Health and Human Services and the administration are committed to working ***now***, before a threat becomes imminent, to thoroughly examine these issues, to make decisions on how to direct **federal** resources, to engage in a dialogue with our constituents and to help put in place the state and local mechanisms that, while they aren't

guaranteed to stop a pandemic in its tracks, can lessen its impacts on our society and ultimately save countless lives.